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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

[Docket No. 02D–0467]

"Guidance for Industry: Recommendations for the Assessment of Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection;" Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled "Guidance for Industry: Recommendations for the Assessment of Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection" dated October 2002. The guidance document provides recommendations for assessing donor suitability and product safety for donors diagnosed with West Nile Virus (WNV) infections or with illnesses potentially caused by WNV. The guidance applies to Whole Blood and blood components intended for use in transfusion and blood components including recovered plasma, Source Leukocytes, and Source Plasma intended for use in further manufacturing into injectable or non-injectable products. These recommendations are intended to reduce the risk of transfusion transmitted WNV, particularly in areas where human cases are occurring.

DATES: Submit written or electronic comments on agency guidances at any time.

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ADDRESSES: Submit written requests for single copies of this guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Nathaniel L. Geary, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled "Guidance for Industry: Recommendations for the Assessment of Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection" dated October 2002. To address the possible risk of transmission of WNV by blood transfusion, we are providing recommendations for donor deferral, and for product quarantine and retrieval related to reports of post-donation illnesses in the donor, or WNV infection in recipients of blood. We

are continuing to consult with experts on WNV at the Centers for Disease Control and Prevention (CDC) and elsewhere to ensure the greatest possible safety of the blood supply. In addition, epidemiologic and laboratory investigations are rapidly evolving. We will evaluate promptly any new data or experiences related to this issue and provide further updates as appropriate. FDA developed the recommendations in the guidance with other Public Health Service agencies of the Department of Health and Human Services.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance document represents the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations.

II. Comments

The agency is soliciting public comment, but is implementing this guidance immediately because of public health concerns related to the possible risk of transfusion transmitted WNV. Interested persons may, at any time, submit written or electronic comments to the Dockets Management Branch (see **ADDRESSES**) regarding this guidance document. Two copies of any mailed comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/cber/guidelines.htm or http://www.fda.gov/ohrms/dockets/default.htm.

Dated: 11-15-02

November 15, 2002.

Margaret M. Dotzel,
Assistant Commissioner for Policy.

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